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Retrospective observational multicenter study on patients treated with a non-animal origin cross-linked hyaluronic acid with different molecular weights for nasolabial folds (Article)

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Abstract

Background: According to the American Academy of Aesthetic Plastic Surgeons, more than 11 million cosmetic surgical and nonsurgical procedures were performed by board-certified plastic surgeons, dermatologists and otolaryngologists in the United States, totaling more than 12 billion dollars. Of that

total, more than 7 billion was spent on surgical procedures and more than 5 billion was spent on nonsurgical procedures. More than 1,872,172 people received Hyaluronic Acid (HA) injections in 2013. Moreover, filler treatments are the most popular procedures performed by dermatologists. Objective: Evaluate, with a new imaging system, durability, efficacy and safety of a nasolabial fold treatment with a cross-linked HA of non-animal origin with different molecular weights. Material and methods: A cross-linked HA (25 mg/ml, 1000-2000 kDa, 23 ± 3 Newton [N] extrusion force, 1,4-Butanediol Diglycidyl Ether (BDDE) content < 0.1 ppm) was used in order to perform the treatment. The product is commercially available with the trademark Aliaxin®GP (Global Performance) and distributed by IBSA Farmaceutici Italia Srl. 25 female subjects aged 40 and 60 years with a photoageing level III according Rubin or type III according Glogau were recruited for the treatment and 0.5 ml of the product were injected for single nasolabial fold. The aesthetic result and the duration of the aesthetic correction were evaluated by the analysis of the skin microreliefs through confocal microscopy and by Glogau's Scale. Additionally, pictures of each patient were collected by Canon PowerShot G10 Digital Camera (14.7 megapixels) before and after treatment. Below the description of the experimental schedule: T0: Baseline, evaluation and treatment; T1: second visit, 4 months after the treatment; T2: third visit, 6 months after the treatment. Results: From 25 patients, 150 silicone casts were obtained: 75 casts of the right nasolabial fold and 75 casts of the left nasolabial fold. Roughness arithmetical average (Ra) was assessed by profilometry. This parameter represents the arithmetic mean deviation of the profile points compared to the average value. The Ra of the right fold at T2 decreased by 50% versus T0 and by 40% compared to T1; Ra of the left fold at T2 decreased by the 45% versus T0 and by 35% compared to T1. No side effects were reported during the observation period beyond mild symptoms (pain, sensation of heat, reddening in the injection site) also described by the product technical sheet. Conclusion: The results proved the efficacy and safety of the nasolabial folds treatment with the tested product and the durability of the aesthetic correction.

Author keywords

Aliaxin®GP; Confocalmicroscopy; Hyaluronic acid fillers; Profilometry